

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

HORIZON MEDICINES LLC and NUVO
PHARMACEUTICALS (IRELAND)
DESIGNATED ACTIVITY COMPANY,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES INC.
and DR. REDDY'S LABORATORIES
LTD.,

Defendants.

Case No. 2:15-cv-03324 (SRC) (CLW)

(Return Date: February 7, 2022)

**DRL'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO
BIFURCATE THE ISSUES OF WILLFULNESS AND DAMAGES FROM
LIABILITY**

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INTRODUCTION

The conduct and order of evidence at trial is one of the core components of the discretion granted to the trial judge, and the caselaw reflects the Court's broad discretion to decide bifurcation. While Plaintiffs argue in their Opposition ("Opp.") to DRL's motion that the jury *could* understand all the issues when combined, or that juries *have* wrestled with complicated facts and legal topics simultaneously, they cannot show that doing so here would be the *best* trial plan for the jury. Indeed, it would not. Here, a bifurcated trial would separate the evidentiary and legal issues cleanly and lead to a fairer and more comprehensible evidentiary presentation.

As discussed further below, Plaintiffs have not controverted this analysis. First, authority cited by both parties supports DRL's request here; Plaintiffs' claim that bifurcation for a phased trial is only granted for "exceptional" cases is inconsistent with this Court's precedent. Second, the jury's comprehension of the legal issues, expert testimony, and factual disputes would undoubtably be enhanced by bifurcation. Third, Plaintiffs get the prejudice analysis wrong—bifurcation will not risk an inefficient trial and will avoid substantive prejudice to DRL. Fourth, bifurcation presents a clear opportunity to preserve both judicial and private resources. Finally, DRL reiterates its alternative request for relief: if this Court denies bifurcation, DRL should be allowed to present its invalidity defense first at trial prior to Plaintiffs' damages and willfulness case.

I. CASES AMPLY SUPPORT BIFURCATION OF A PATENT TRIAL OF THIS SIZE AND SCOPE.

Decisions of this Court, including decisions by Your Honor, support bifurcation, and the exercise of broad discretion in determining whether to bifurcate, here. As courts have repeatedly explained, “[t]his decision is left to the sound discretion of the Court.” *Princeton Biochem. Inc. v. Beckman Instruments Inc.*, 180 F.R.D. 254, 256 (D.N.J. 1997); *see also Robert Bosch, LLC v. Pylon Mfg. Corp.*, 719 F.3d 1305, 1319 (Fed. Cir. 2013) (*en banc*) (“[W]e wish to make clear that district courts, in their discretion, may bifurcate willfulness and damages issues from liability issues in any given case.”); *Ricoh Co. v. Katun Corp.*, 2005 WL 6965048, at *1 (D.N.J. July 14, 2005) (cited by Opp. at 3) (“The Court has broad discretion in deciding whether to separate issues and claims for trial, in accordance with its broad power to manage its trial calendar.”). Patent cases often offer ideal circumstances for bifurcation: “Bifurcation of complex patent disputes has become a common occur[r]ence.” *Ricoh*, 2005 WL 6965048, at *1 (granting bifurcation of antitrust counterclaims); *see also Princeton Biochem.*, 180 F.R.D. at 258 (granting bifurcation in patent case and finding case “ripe for bifurcation”).

Though Plaintiffs cite to *Depomed Inc. v. Purdue Pharma L.P.*, 2013 WL 6190380 (D.N.J. Nov. 26, 2013), three separate times for the quote that bifurcation “remains the exception rather than the rule” (Opp. at 1, 3, 5), that case is inapplicable for at least three reasons.

First, Depomed concerned a procedurally different question and is therefore distinguishable. There, the Court grappled with whether to bifurcate and *stay damages discovery* until *after* a separate liability jury trial. *Id.* at *1. The Court declined to do that because the case was “in the early stages of proceedings” and, unlike here, the plaintiff was pursuing legal contentions that substantially overlapped between liability and damages, such as commercial success to prove nonobviousness. *See id.* at *5, *8. In fact, all but *one* of the cases Plaintiffs cite in Section A of the Opposition concern motions to bifurcate and stay discovery.¹ The prospect of delaying even *discovery* into damages and willfulness potentially for years raises a significantly higher hurdle for a party seeking bifurcation to cross, and

¹ *See Synopsys, Inc. v. Magma Design Automation*, 2006 WL 1452803, at *4 (D. Del. May 25, 2006) (Opp. at 4); *Real v. Bunn-O-Matic Corp.*, 195 F.R.D. 618, 619 (N.D. Ill. 2000) (Opp. at 4); *DSM Desotech Inc. v. 3D Sys. Corp.*, 2008 WL 4812440, at *1 (N.D. Ill. Oct. 28, 2008) (Opp. at 5); *Lutron Electronics Co. v. Crestron Elecs., Inc.*, 2010 WL 2024510, at *1 (D. Utah May 19, 2010) (Opp. at 8); *Arendi Holding Ltd. v. Microsoft Corp.*, 2009 WL 3535460, at *1 (D. Del. Oct. 27, 2009) (Opp. at 8); *Schneider (USA), Inc. v. Cordis Corp.*, 1993 U.S. Dist. LEXIS 15213, at *11-12 (D. Minn. May 8, 1993) (Opp. at 9); *Sprinturf, Inc. v. Sw. Recreational Indus., Inc.*, 2004 WL 96751, at *2 (E.D. Pa. Jan. 15, 2004) (Opp. at 10); *Ranco Inc. of Del. v. Caleffi N. Am., Inc.*, 2005 WL 8179197, at *1 (N.D. Ill. Aug. 22, 2005) (Opp. at 10); *SenoRx, Inc. v. Hologic, Inc.*, 920 F. Supp. 2d 565, 570 (D. Del. 2013) (Opp. at 13).

The one case Plaintiffs cite that does not concern a discovery stay involved a proposal to bifurcate *a defendant’s counterclaims*, and would have entailed “two trials with two juries, potentially involving four weeks, rather than one trial involving similar technologies, scheduled for two weeks.” *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 498 F. Supp. 2d 734, 737 (D. Del. 2007) (Opp. at 8). The court expressly distinguished that request from those seen in other “complex patent infringement cases” in which “liability issues ... may be separate and distinct from damages issues.” *Id.*

the analysis in those cases is not applicable here. *See, e.g., id.* at *9 (noting wasted resources from discovery disputes and prejudice in “inevitable delay” from separated trials). Here, in stark contrast, discovery is closed following more than a decade of document production and expert testimony, DRL’s bifurcation request would delay nothing, and bifurcation requires only a single jury, without any pause between trial phases. All of this is true precisely *because* the record is fully developed and the contested legal issues have no significant overlap.

Second, there is no requirement in the discretionary Rule 42(b) analysis that the Court grant relief only in “exceptional” cases (*see* Opp. at 4 n.1). Indeed, some judges (though, consistent with the discretionary nature of the decision, not all) have articulated precisely the opposite tendency in the patent context, writing “bifurcation is appropriate, if not necessary, in all but exceptional patent cases.” *Dutch Branch of Streamserve Dev. AB v. Exstream Software, LLC*, 2009 WL 2705932, at *1 (D. Del. Aug. 26, 2009).² And in *Medpointe Healthcare Inc. v. Hi-Tech Pharmacal Co.*, 2007 WL 188285, at *5 (D.N.J. Jan. 22, 2007), where this Court granted the same type of bifurcation that DRL seeks here, it stated “[i]n patent cases, bifurcation of liability and damages is not uncommon,” not an exception only.

² *See also Ciena Corp. v. Corvis Corp.*, 210 F.R.D. 519, 521 (D. Del. 2002) (“This Court has conducted many patent jury trials and spoke with numerous juries in post-trial meetings. From these post-trial discussions with jurors and attorneys, the Court has determined that the use of alternative trial procedures could assist juries in obtaining a better understanding of the legal issues they are called upon to decide.”).

Third, whether or not *most* patent cases should be bifurcated does nothing to answer the question of whether, in *this* case, bifurcation would conserve resources, improve juror comprehension, and avoid prejudice. Ultimately, “[i]n deciding whether one trial or separate trials will best serve the convenience of the parties and the court, avoid prejudice, and minimize expense and delay, the major consideration is directed toward the choice most likely to result in a just final disposition of the litigation.” *In re Innotron Diagnostics*, 800 F.2d 1077, 1084 (Fed. Cir. 1986). Here, bifurcation achieves that end.

Plaintiffs are also wrong that because this matter is supposedly “a comparatively simple patent infringement case,” bifurcation is inappropriate. (Opp. at 1.) This Court in *Princeton Biochemicals* too rejected the argument of the plaintiff that “the instant matter is a relatively simple patent case.” *Princeton Biochem.*, 180 F.R.D. at 257 & n.1 (“Even plaintiff’s most simplistic assessment of the underlying technology and the liability issues in question are likely to be confusing to a jury, unsophisticated in the area of intellectual property.”). More directly, Your Honor granted bifurcation of a patent matter in precisely the way that DRL now requests: separating liability from damages before the same jury. Minute Entry and Trans. of Daubert Hearing, *Mondis Tech. Ltd. v. LG Elec.*, No. 15-4431 (Mar. 22, 2019, D.E. 427, 591) (Chesler, J.). That decision came in a (per plaintiffs) one-patent dispute with a trial estimate of 4-5 days—so arguably a case less complex than this one, and

certainly not more. *See* Pls.’ Br. in Opp. to Mot. to Bifurcate, *Mondis Tech.*, at 9-10 (Mar. 15, 2019, D.E. 414) (“The parties’ trial estimate is 4-5 days. There is one patent and three claims at issue. . . . The damages case is also simple . . .”). Plaintiffs have no response, and do not even discuss *Mondis*.³

II. JUROR COMPREHENSION WOULD BENEFIT BY ADDRESSING THE ISSUES OF THIS CASE SEPARATELY.

DRL’s request for bifurcation is not based simply on the fact that *some* legal and factual issues are different between liability and damages—an aspect true of nearly any trial involving damages—but that, in this case in particular, the burdens of proof, standards of proof, and experts are *entirely distinct* between the two phases, and the factual evidence virtually so. Indeed, the stipulation to infringement in this matter makes this case particularly ripe for bifurcation. Here, on liability, because infringement is not contested, *only* DRL has the burden of proof, and the standard of proof is clear and convincing evidence. On damages and willfulness, *only* Plaintiffs have the burden of proof, and the standard of proof is preponderance of the evidence. This arrangement of burdens is not always the case in patent matters, such as where infringement may be contested. But here, the issues and legal standards divide cleanly. Certainly, it would be more comprehensible for the jury

³ Another factor present in *Mondis*, also present here, was that prior judgments on related patents were relevant at some phases of the trial but not others. *See* Trans., *Mondis Tech.*, at 167-68 (Dec. 20, 2019, D.E. 591).

to handle those separate issues separately—and Plaintiffs do not argue otherwise. Instead, Plaintiffs argue that juries “can” handle unified cases with complex issues. (*See* Opp. at 4-5.) But the goal is to ensure this case is “resolved in a just manner by [a] jur[y] that understand[s] the complex issues before [it],” not to deny a sensible trial plan based on whether juries have been tasked with handling as much before. *Ciena*, 210 F.R.D. at 521. On that score, bifurcation is better.

The same is true of the factual and expert evidence. Plaintiffs’ claim that “the issues are closely interwoven in the liability stage and the willfulness and damages stage” (*see* Opp. at 20-21) is not consistent with their representations to this Court of the evidence and witnesses in the Proposed Pretrial Order or in other parts of their Opposition. Plaintiffs admit that there are “four validity experts” and “four damages experts”—thus, entirely distinct. (Opp. at 8.)⁴ Every “contested fact” Plaintiffs listed in the Proposed Pretrial Order concerned damages—because in Plaintiffs’ words, “Plaintiffs have no burden of proof regarding” DRL’s invalidity defense—showing again the distinct issues. (Proposed Pretrial Order at 19-20 & n.2.) Only one fact witness potentially overlaps per side, and even then only barely. As DRL previously explained in its opening memorandum (D.E. 450 at 9 & n.4), and as Plaintiffs do not contest now, the proffered testimony of their one partly-overlapping

⁴ Moreover, in Plaintiffs’ opposition summary judgment briefing, Plaintiffs made no reference to the liability experts at all when opposing DRL’s separate requests for summary judgment on damages and on willfulness. (*See* D.E. 441 at 25-30.)

witness, Mr. Camardo, “relates entirely to events that occurred years after the relevant date for invalidity and concern[s] financial issues.” The overwhelming majority of his testimony would be confined to the damages phase. And why the jury would need to “understand the patents at issue” to assess damages (*see* Opp. at 21), Plaintiffs do not say.⁵ Even so, DRL’s proposed bifurcated trial plan resolves that concern. Since *the same jury* will decide both phases and since liability will be determined first, the jury will have no need to be reeducated on the patents.

In addition, while Plaintiffs now argue that this matter is “comparatively simple,” (Opp. at 1), that is the *opposite* of what Plaintiffs have told this Court up until now. Plaintiffs have repeatedly emphasized the “highly fact specific” nature of the written description issue the jury will have to decide. (*E.g.*, D.E. 325 at 12; D.E. 441 at 8 (both quoting *Nuvo Pharms. (Ireland) DAC v. Dr. Reddy’s Lab’ys, Inc.*, 923 F.3d 1368, 1383 (Fed. Cir. 2019)).) And they have pointed insistently to voluminous reports submitted by “dueling experts” on the scope of the patents-in-suit to support their position that, notwithstanding the Federal Circuit’s decision in *Nuvo*, there are significant disputes of material fact precluding summary judgment

⁵ This contention is also inconsistent with the reports of Plaintiffs’ proffered expert on damages, Dr. Mohan Rao. Dr. Rao’s analyses in his reports do not depend on the patents-at-issue themselves or the asserted claims, except for their expiration date. The patents-at-issue concern a single product relevant to Plaintiffs, Vimovo. There are no patent-specific considerations in his economic analysis. (*See* D.E. 437-13 (Rpt. of Dr. Rao); D.E. 437-17 (Reply Rpt. of Dr. Rao).)

of invalidity. (*E.g.*, D.E. 441 at 9.)⁶

Further, damages in this case are more complicated for a jury than Plaintiffs let on. Few juries could be expected to be familiar with the forecasting analysis performed by damages experts on each side. Nor is a jury likely familiar with the *Georgia-Pacific* factors analysis conducted by Mr. Ivan Hoffman, one of DRL's experts concerning damages. Indeed, if the damages were a simple accounting exercise, there would be no need for expert testimony at all. *See, e.g., Foraker v. Schauer*, 2005 WL 6000493, at *5 (D. Colo. Sept. 8, 2005) ("Jurors can add and subtract, and if [the expert's] sole function is to perform this role, plaintiffs do not need an expert."). Moreover, Plaintiffs' argument that "damages are straightforward" (Opp. at 8), ignores DRL's two other proffered experts: Dr. James Seibold, who is expected to testify concerning Vimovo's therapeutic use, and Sandra Kinsey, who is expected to testify concerning pharmaceutical retail and market dynamics. Both are relevant to the second *Panduit* factor, the existence of acceptable non-infringing alternative products. *See Panduit Corp. v. Stahl Bros. Fibre Works*, 575 F.2d 1152, 1156 (6th Cir. 1978). In sum, damages in this case are not arithmetic. Instead, the jury may need to weigh and consider the testimony of four experts, forecasting analyses, accounting principles, non-infringing alternative and market

⁶ Plaintiffs also mistake the scope of the invalidity issues for trial. There is not "a single asserted invalidity defense." (Opp. at 2.) DRL has two separate written description defenses at trial, as explained in DRL's opening brief (D.E. 450 at 1, 8).

analyses, *Panduit* factors, and *Georgia Pacific* factors. There is no need to tackle that at the same time as invalidity.

At bottom, there is every reason to think that the jury will be confused by taking the issues in backwards order (damages first, liability second). The more logical sequence is to begin at the beginning, with liability, followed by damages if Plaintiffs' case survives threshold questions of invalidity. Plaintiffs have no convincing argument why that more logical sequence is not also the one that best promotes juror comprehension.

III. PLAINTIFFS' ANALYSIS OF THE PREJUDICE IS INCORRECT.

DRL faces obvious prejudice if damages and DRL's supposed willful infringement are put to the jury before DRL can present its arguments for why it is not liable for any damages in the first place. Plaintiffs' case would start off as if liability were already established. After being presented with hours, or perhaps days, of evidence on Plaintiffs' alleged damages and how DRL allegedly "deliberately and intentionally infringed the presumptively valid" asserted claims (D.E. 441 at 30), jurors will be hard-pressed to forget that evidence and rewind to the antecedent question of whether DRL infringed valid patents at all. Presenting the issues backwards threatens DRL's ability to present its substantial invalidity defenses fairly.

Plaintiffs (Opp. at 17-18) all but ignore these concerns, except to accuse DRL

of complaining about “self-imposed prejudice,” which presumably refers to DRL’s stipulation on infringement. But pointing to the stipulation proves the opposite point from the one Plaintiffs are trying to make. Defendants in patent cases stipulate to infringement to narrow the disputes at issue and conserve resources, not to allow plaintiffs to bypass liability and start with damages at trial. If the latter were the inevitable consequence of stipulating to infringement, few defendants would do so.

Plaintiffs then (Opp. at 18-21) march through a list of injuries they supposedly will suffer from bifurcation, but nothing from that parade of horrors adds up. Costs and uncertainty around the trial timeline will not increase, because, if necessary, the same jury will immediately proceed from a trial on liability to a trial of damages. Concerns about scheduling witnesses are true regardless of whether the trial is bifurcated. Considering the parties believe that the evidentiary presentation will take at most five days (and Plaintiffs think three), juror deliberations can hardly be expected to take so long as to throw a wrench in the trial plan. If anything, bifurcating the issues will keep the jurors focused on the relevant issues and undistracted by irrelevant ones as they deliberate.

Further, because there is no delay between phases, bifurcation will not add to the risk of losing jurors as the trial progresses. Similarly, there is little risk jurors will violate their oaths and tip the scales in favor of DRL simply to save a few days’ work. This Court has already made short work of that argument. *See Medpointe,*

2007 WL 188285 at *3, 7. And the jury could be instructed on bifurcation in a way that avoids prejudice. *See* Tr. Trans., *Mondis Tech.*, at 27-28 (Dec. 20, 2019, D.E. 592) (instructing jury on bifurcation). Plaintiffs respond (Opp. at 19) by arguing that the *Medpointe* decision court “merely mentioned this argument”—which is just another way of admitting that this Court specifically noted the argument and rejected it.⁷ The Court should do so again here.

Finally, Plaintiffs claim (Opp. at 20) that because “the issues are closely interwoven in the liability stage and the willfulness and damages stage,” they would be prejudiced by having to re-present the same evidence for damages. Not so. Plaintiffs’ own submissions to this Court show why. As already explained, *see supra* at 7-8, the Pretrial Order Plaintiffs co-authored makes clear there is sparingly little connection between the contested facts and the fact witnesses on liability and those on damages and no overlap between the experts for those phases. Particularly where this Court has previously rejected claims of prejudice where *over a dozen* witnesses overlapped between trial phases, this argument falls flat. *See Medpointe*, 2007 WL 188285, at *6 (describing “relatively minor degree” of prejudice where 16 out of 39

⁷ Plaintiffs suggest (Opp. at 19) that *Giglio v. Am. Fam. Mut. Ins. Co.*, 2010 WL 11578875, at *2-3 (D. Nev. Mar. 25, 2010), supports their argument on juror incentives, but that out-of-circuit decision concerned the bifurcation of separate breach of contract and bad faith claims concerning “evidence and testimony . . . so intertwined and overlapping that much of the same evidence and same testimony would be required to establish both kinds of claims.” This inapposite example does not show prejudice to Plaintiffs in the situation here.

total witnesses overlapped). In short, Plaintiffs can point to no material hardship if liability were tried first.

IV. BIFURCATION WOULD PRESERVE JUDICIAL AND TRIAL RESOURCES.

The Court has already recognized that this case presents a “substantial question of patent validity.” (DE 252 at 16.) Based on this assessment, there is a significant possibility the case can be decided on liability grounds alone. Given that, the most efficient plan is to try liability first, and only try damages in the event DRL’s “substantial” invalidity defenses are unsuccessful. That is not “speculation” (*see* Opp. at 13), but rather appropriate and sensible pragmatism in light of this case’s merits. Once again, Plaintiffs’ authorities on the issue are inapposite, because they concern motions to bifurcate *and stay discovery* early in the life of a case, when the court’s views on the merits had yet to crystalize. *See SenoRx*, 920 F. Supp. 2d at 570 (cited by Opp. at 13); *Sprinturf*, 2004 WL 96751, at *2 (same). Similarly, Plaintiffs raise concerns (Opp. at 13-14) about “two sets of jury instructions, two sets of deliberations, and other additional delays,” but that merely begs the question whether the jury will likely need to reach damages if they are allowed to consider liability first. The answer to that question is no. Further, with the phases of trial occurring over the course of only a few days, there is no need for the jury to receive substantially duplicative instructions in both phases.

The ongoing COVID pandemic does not create the presumption against

bifurcation that Plaintiffs suggest. (*See* Opp. at 15-16.) This Court can and should consider the effects of COVID on the trial, but based on conditions at the time the Court sets for trial. Plaintiffs’ cases merely illustrate that during past phases of the pandemic and in case-specific circumstances, some courts have decided against bifurcation—as when, for example, a “[t]rial has” already “been delayed repeatedly” by COVID, *Snyder v. Bank of Am., N.A.*, 2020 WL 6462400, at *12-13 (N.D. Cal. Nov. 3, 2020) (cited by Opp. at 15), or when then-current pandemic conditions and the “uncertainty of the defendant’s success on the issue of liability” together suggested bifurcation would not streamline proceedings, *Saunders v. Metro. Prop. Mgt., Inc.*, 2021 WL 4303776, at *2 (W.D. Va. Sept. 2, 2021) (cited by Opp. at 15 n.4). In other decisions Plaintiffs do not cite, courts have concluded that then-current pandemic conditions *avored* bifurcation—particularly where, as here, there was a distinct possibility that the case could be decided at the liability stage.⁸

⁸ *E.g.*, *Matter of M/V UNCLE ROBERT*, 2020 WL 3576839, at *2 (E.D. La. July 1, 2020) (ordering bifurcation because resolution of liability would “eliminate[] or reduce[]” the need for a damages trial, and, “considering the severity of risks posed to the public, trial participants, and Court staff caused by the Coronavirus Disease (COVID-19), the Court finds that bifurcation will limit exposing trial participants to each other unnecessarily as much as possible”); *Transparent Energy, LLC v. Premiere Mktg., LLC*, 2021 WL 6200910, at *1 (N.D. Tex. Dec. 30, 2021) (“[B]ifurcation will aid in the efficient use of judicial resources—especially as the Court endeavors to manage unprecedented demands on its docket and safety concerns of potential jurors during the ongoing pandemic. There is great benefit to the jury, if it decides liability in [defendant’s] favor, as it will not have to spend any extra time in court hearing damages testimony.”).

The upshot is that COVID is one of many factors for the Court to consider in the discretionary bifurcation analysis. Given that a trial has not even been scheduled for this case, there is simply no way to know how the pandemic will impact the trial, and an attempt to weigh those considerations now is premature. Depending on the circumstances, the Court may well conclude that pandemic-related considerations tip in favor of bifurcation, just as the other factors DRL has laid out above do.

V. DRL MAINTAINS ITS ALTERNATIVE REQUEST TO PRESENT EVIDENCE ON LIABILITY FIRST.

For the reasons given, the Court should bifurcate the trial into two phases. But if the Court disagrees, it should at least allow DRL to begin the trial with its invalidity case. As DRL explained in its opening brief (D.E. 450 at 15-16), the Court has discretion to “exercise reasonable control over the mode and order of examining witnesses.” Fed. R. Evid. 611. Given that DRL bears the burden of proof on the remaining liability questions, the necessary threshold issue at trial, DRL should be allowed to present its case in chief on that issue first.

CONCLUSION

For the above reasons and as described in its opening brief, DRL respectfully requests that the Court order that trial in this case be bifurcated into two consecutive phases tried by the same jury.

Dated: January 31, 2022

Respectfully submitted,

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